: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Delegation of Authority Under Section 564A(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3a(e))

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: CDC has redelegated the authority under the Federal Food, Drug, and Cosmetic (FD&C) Act to create and issue amended emergency use instructions (EUI) to inform healthcare providers or individuals to whom an eligible product, as defined under the FD&C Act, is to be administered, concerning the product's approved, licensed, or cleared conditions of use that deviate from approved labeling, standard clinical practice, and/or standard medical modality (e.g., individual prescription within the patient-clinician relationship). This notice announces the redelegation of the above-mentioned authority, without the authority to redelegate, from the Director, CDC, to the Director, National Center for Immunizations and Respiratory Diseases (NCIRD).

DATES: This delegation was approved by the Director, CDC, and is effective October 28, 2022.

SUPPLEMENTARY INFORMATION: Only the Director, CDC, can issue original EUIs. The Director, NCIRD, may only issue amendments that are substantially within the scope of the original EUI and only for countermeasures within the scope of the NCIRD Director's official responsibilities. This authority shall be exercised under section 564A(e) of the FD&C Act (21 U.S.C. 360bbb-3a(e)), and any related HHS policies. This delegation became effective on

October 28, 2022. The Director, CDC, affirms and ratifies any actions taken that involve the exercise of the authority delegated herein prior to the effective date of this delegation.

Sherri A. Berger,

Chief of Staff,

Centers for Disease Control and Prevention.

[FR Doc. 2022-24044 Filed: 11/3/2022 8:45 am; Publication Date: 11/4/2022]